DECLARATION OF LARRY D. SASICH

January 26, 2014

1. My name is Larry D. Sasich, PharmD, MPH, FASHP. I am over the age of twenty-one and competent to testify to the truth of the matters contained herein. The factual statements I make in this declaration are true and correct to the best of my knowledge and experience. The opinions I express in this statement are made to a reasonable degree of scientific certainty.

2. I am a Consultant specializing in drug safety and efficacy issues. My background, experience and qualifications, in part, include:

a. Serving as a consultant to the Saudi Food and Drug Authority, Riyadh, Saudi Arabia.

b. Serving as Chairperson of the Department of Pharmacy Practice at the LECOM School of Pharmacy in Erie, Pennsylvania, from 2007 to 2009;

c. Serving as a consultant to Public Citizen Health Research Group, Washington, D.C., and

d. Serving as a Consumer Representative on the Science Board of Food and Drug Administration's, an advisory committee to the FDA Commissioner.

3. I have a Masters in Public Health, with an emphasis in biostatistics and epidemiology from the George Washington University, and a Doctorate of Pharmacy from University of the Pacific. I have completed a residency in nuclear pharmacy at the University of New Mexico. I have also been elected a Fellow in the American Society of Health-System Pharmacists (FASHP). I have also authored publications and/or presented analysis on drug safety issues. A complete list of my publications and presentations are listed in my Curriculum Vitae, which is appended to this Declaration as Exhibit A.

4. Counsel representing Missouri death-sentenced prisoner Mr. Herbert Smulls, who is scheduled for execution on January 29, 2014, have asked me to offer opinions on representations made in the document "Suggestions In Opposition To Plaintiff Smulls's Motion For Stay Of Execution" prepared by the Office of the Missouri Attorney General. There are several important issues that were not addressed in this document.

5. The Office of the Missouri Attorney General ignored the fact that

the contract-testing laboratory reported an unknown residual solvent yet *passed* the sample. The injection of an unknown substance into a prisoner or anyone for that matter carries a very substantial risk of causing pain and suffering to the recipient.

6. The failure of Missouri officials to disclose the formula and records regarding the preparation of the pentobarbital sodium injection makes it impossible to give a full and complete opinion in this matter at this time. This information is *essential* to a proper review of the compounded drug.

7. [redacted]

8. [redacted]

9. To the best of my knowledge there is no government oversight, either state or federal, [redacted] this element of the pharmacy compounding industry has a record of shoddy performance that has resulted in the public being harmed.

10. The Attorney General asserts that because [redacted] pentobarbital sodium injection, it can be stored at room temperature 30 days. As stated, it is my opinion that these test results by [redacted] relied upon. Further, the USP defines room temperature as a *controlled* room temperature that is thermostatically controlled in the range of 68^0 F to 77^0 F. Drugs stored outside this range are considered adulterated.

11. Missouri must produce temperature logs documenting that in fact the pentobarbital sodium injection was continuously stored at controlled room temperature. This would include the transport of the drug from the compounding pharmacy in Oklahoma to the execution site in Missouri.

Conclusion

12. The Attorney General has failed to address important issues about the safety, effectiveness, and purity of the compounded pentobarbital sodium injection that was purchased from an Oklahoma compounding pharmacy. These issues include the presence of an unknown residual solvent.

13. The State is relying on test results that cannot be considered reliable because they are from a discredited contract-testing laboratory, [redacted] In addition, there is no documentation that the pentobarbital sodium injection has been stored at a controlled room temperature.

14. Based on these serious issues, there is a very substantial likelihood that Mr. Smulls will be injected with an unsafe compounded drug that will cause him to suffer extreme pain and harm.

I declare under pains and penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Larry D. Smith 1/26/14

Larry D. Sasich, PharmD, MPH, FASHP

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 N. Central Expressway, #300 Dallas, TX 75204 214-253-5200 Industry Information: www.fda.gov/oc/industry	10/12/12-11/08/12
	FEI NUMBER [redacted]

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: [redacted]

FIRM NAME	STREET ADDRESS
[redacted]	[redacted]
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
[redacted]	Contract Testing Laboratory

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

The following observations pertain to the firm's contract testing of human drug products, including compounded drug products.

1. Your firm states on the Microbiology Report that is issued to a client after sterility and/or fungal testing that the Test Method employed was USP <71>. However, your firm is not fully following all parts of USP <71> when performing sterility and/or fungal testing of human drug products. For example,

a. USP <71> requires a Method Suitability Test be performed for all new products tested. Your firm does not have documentation to show that Method Suitability Testing has been performed for all drug products submitted for sterility testing by [redacted] both located in [redacted] For those drug products submitted by [redacted] you have some documentation of bacteriostasis/fungistasis testing performed in 2006 & 2008 on a limited number of drug products, however there is no source documentation showing how the tests were performed, lot numbers of organisms or media used, and who performed the testing.

b. USP <71> specifies the number of articles to be tested. While you provide reference to USP <71> for sample sizes, you do not ensure that your clients are submitting the required number of articles for testing. Most clients usually submit only (b) (4) for sterility testing, including [redacted]

2. Your firm has no documentation to show that all analytical methods used to test for potency (assay) have been validated for all drug products including drug products submitted for testing by [redacted] These include drug products such as Methylprednisolone Acetate, Heparin, Vasopressin, Triamcinolone Acetonide, and products containing Bupivacaine and Epinephrine. Analytical methods that are not validated and/or not found in the USP that are used for potency testing of human drug products are not written, reviewed and approved.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	[redacted]	[redacted]	11/8/12

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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4040 N. Central Expressway, #300 Dallas, TX 75204 214-253-5200 Industry Information: www.fda.gov/oc/industry	10/12/12-11/08/12
	FEI NUMBER [redacted]

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: [redacted]

FIRM NAME	STREET ADDRESS
[redacted]	[redacted]
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
[redacted]	[redacted]

3. Your firm states on the Microbiology Report that is issued to a client after endotoxin testing that the Test Method employed was USP <85>. Your firm is not fully following all parts of USP <85> when performing endotoxin testing of human drug products.

Specifically, the Maximum Valid Dilution (MVD) is not always calculated using the formula in USP <85>. Your firm does not ensure that each of your clients provides information regarding dosing of the drug product needed to calculate the MVD. For example,

a. An endotoxin limit was not established for Clonidine/Ropivacaine (PF) 1mcg/1mg/ml in 500mL 0.9% Sodium Chloride (injectable) submitted as sample #186092-01 by [redacted] and tested for endotoxins on 9/4/12.

b. An endotoxin limit was not set for Baclofen PF (STOCK) 5000 mcg/mL Injection submitted as sample #184445-01 by [redacted] and tested for endotoxins on 9/4/12.

c. An endotoxin limit was not set established for CP2D submitted as sample #176189-01 by [redacted] and tested for endotoxins on 5/18/12.

4. Your firm has had 13 confirmed endotoxin failures for various drug products from October 2010-October 2012. There is no documentation of any investigations conducted into any endotoxin failures, including the failure of sample #186077-01 of Sodium Bicarbonate 150mEq/1000mL in Sterile Water for Injection that was submitted by [redacted] SOP MBI-126 Microbiology Out-of-Specification Investigation (OOS), does not address investigation of OOS's for endotoxin testing.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	[redacted]	[redacted]	11/8/12

CURRICULUM VITAE

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839 Main Street West #3
North Bay, P1B 2V8, Ontario
Canada
Cell Phone: 705-491-0609
E-Mail: larry.sasich@gmail.com

EDUCATION

1995 to 1997	Master of Public Health - Epidemiology The George Washington University School of Public Health and Health Services Washington, D.C.
1974 to 1975	Doctor of Pharmacy University of the Pacific College of Pharmacy Stockton, California
1966 to 1970	Bachelor of Science Pharmacy Idaho State University College of Pharmacy Pocatello, Idaho

RESIDENCY

1986 to 1987	Nuclear Pharmacy University of New Mexico College of Pharmacy Albuquerque, New Mexico

PROFESSIONAL LICENSES

1970 to Present	California RPH 27094

PROFESSIONAL EXPERIENCE

April 2013 to date	Consultant, Drug Policy, Drug Safety and Efficacy North Bay, ON Canada
July 2007 to April 2013	Consultant, Saudi Food and Drug Authority 3292 Northern Ring Rd. Al Nafal District Riyadh, Saudi Arabia
November 2009 to 2012	Consultant, Public Citizen's Health Research Group 1600 20th Street, NW Washington, D.C. 20009
2007 to 2009	Chairman, Department of Pharmacy Practice LECOM School of Pharmacy 1858 Grandview Blvd. Erie, PA 16505
2006 to 2007	Acting Chairman, Department of Pharmacy Practice LECOM School of Pharmacy 1858 Grandview Blvd. Erie, PA 16505
2005 to 2006	Assistant Professor, Department of Pharmacy Practice LECOM School of Pharmacy 1858 Grandview Blvd. Erie, PA 16505
2006 to 2008	Consultant Centre for Science and the Public Interest – Canada Suite 4550, CTTC Bldg. 1125 Colonel By Drive Ottawa, Ontario K1S 5R1 Canada

PROFESSIONAL EXPERIENCE

2005 to 2007	Consultant Public Citizen's Health Research Group 1600 20th Street, NW Washington, D.C. 20009
2005 to 2006	Consultant Canadian Agency for Drugs and Technologies in Health 600-865 Carling Avenue Ottawa, Ontario K1S 5S8 Canada
1995 to 2005	Research Analyst Public Citizen's Health Research Group 1600 20th Street NW Washington, D.C. 20009
1991 to 1995	Drug Information Pharmacist King Faisal Specialist Hospital and Research Centre Riyadh 11211, Saudi Arabia
1993 to 1996	Adjunct Clinical Faculty Welch School of Pharmacy University of Wales Cardiff, Wales
1992 to 1995	Clinical Instructor College of Pharmacy King Saud University Riyadh, Saudi Arabia Graduate and Undergraduate Teaching
1988 to 1990	Clinical Pharmacist St. Helens Hospital and Health Center St. Helens, OR Emanuel Hospital and Health Center Portland, OR
1985 to 1988	Associate Professor of Clinical Pharmacy Idaho State University College of Pharmacy Pocatello, Idaho Promoted and Tenured July 1, 1984

PROFESSIONAL EXPERIENCE

1983 to 1984	Assistant Professor of Clinical Pharmacy College of Pharmacy Idaho State University Pocatello, Idaho
	Acting Associate Dean for Student Affairs
1982 to 1983	Assistant Professor of Clinical Pharmacy College of Pharmacy Idaho State University Pocatello, Idaho
	Director of Professional Practice
1979 to 1982	Assistant Professor of Clinical Pharmacy College of Pharmacy Idaho State University Pocatello, Idaho
	Director, Idaho Drug Information Service and Regional Poison Control Center
1976 to 1979	Assistant Director of Pharmacy Services USA MEDDAC Berlin, West Germany
1975 to 1976	Staff Pharmacist USA MEDDAC Wuerzburg, West Germany
1970 to 1974	Pharmacist Baneth's Pharmacy Menlo Park, CA

HONORARY SOCIETIES

1982	Rho Chi
1982	Sigma Xi

AWARDS

2000	Distinguished Person of the Year – Pharmacists Planning Services
1995	Fellow American Society of Health-System Pharmacists
1986	Ciba-Geigy Leadership Award
1983	Outstanding Service – Idaho Board of Pharmacy
1982	Phi Delta Chi Faculty Achievement Award

APPOINTMENTS

2009	FDA Science Board Sub Committee on the Center for Food Safety and Applied Nutrition (CFSAN)
2008	FDA Science Board Sub Committee on the review of the National Center for Toxicological Research
2007	Grant Reviewer U.K. Economic and Social Research Council Large Grant proposal: Governance of Pharmaceuticals and Health
2007	Consumer representative, Science Board to the Food and Drug Administration – advisory committee to the FDA Commissioner
2007	Pennsylvania Pharmacists Association Pharmacy Compounding Task Force
2006	Food and Drug Administration Pediatric Advisory Committee November 16, 2006 – substitute consumer representative
2006	Reviewer *PLoS Medicine*
2000	Reviewer for the *Western Journal of Medicine*
2000	Reviewer for the *Journal of the American Medical Association*
1996	Department of Health and Human Services Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Drug Information
1996	Department of Health and Human Services, Food and Drug Administration, Consumer Consortium

APPOINTMENTS

1995	Reviewer for the *Saudi Pharmaceutical Journal*
1993	Reviewer for the *Annals of Saudi Medicine*
1986	Reviewer for *Annals of Pharmacotherapy*
1987	Idaho Delegate to Western Regional Conference on Clinical Pharmacy Practice
1985	Idaho Health Systems Ethics Conference Task Force
1984	American Pharmaceutical Association Committee to prepare accreditation standards for a community pharmacy residency
1982	Assistant Editor DRUGDEX®
1981	USP Dispensing Information Contributors Panel

PUBLICATIONS

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Sukkari SR, Sasich LD, Tuttle DA, Abu-Baker A, Howell H. Development and Evaluation of a Required Patient Safety Course. *American Journal of Pharmaceutical Education* 2008; 73(3)

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